Attorney's Docket No.: 19226-002US1 / F/UPS86390

Applicant: Brown et al.
Serial No.: 10/534,634
Filed: May 11, 2005

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Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

- 1. (currently amended) A formulation of a therapeutic substance suitable for delivery to a patient by a metered dose inhalation device, the formulation comprising a substantially dry powder preparation of the substance in association with a stabilising amount of a glycoside carbohydrate compound or derivative thereof and a polyhydroxylated polyalkene in combination with one or more propellants therefor, wherein the therapeutic substance is selected from peptides and proteins.
- 2. (original) A formulation according to claim 1, further comprising a cosolvent for said substance.
- 3. (previously presented) A formulation according to claim 1, wherein the therapeutic substance is selected from antibodies, interferons, enzymes, hormones, euprolide acetate, CFTR, and α 1-antitrypsin.
- 4. (original) A formulation according to claim 3, wherein the therapeutic substance is a hormone selected from insulin, LHRH, granulocyte-colony stimulating factor, calcitonin, heparin, human growth hormone, and parathyroid hormone.
- 5. (original) A formulation according to claim 1, wherein the substance is dnase I.
- 6. (previously presented) A formulation according to claim 1, which is non-immunogenic.

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7. (previously presented) A formulation according to claim 1, which is capable of being stored at room temperature without losing more than 50% biological activity of the therapeutic substance after two months.

- 8. (currently amended) A formulation according to claim 1, wherein the glycoside carbohydrate compound comprises at least one oligosaccharide.
- 9. (currently amended) A formulation according to claim 8, wherein the glycoside carbohydrate compound comprises at least one disaccharide.
- 10. (original) A formulation according to claim 9, wherein the disaccharide is selected from trehalose, mannitol, sucrose, and mixtures thereof.
- 11. (currently amended) A formulation according to claim 1, wherein the glycoside carbohydrate compound or derivative thereof constitutes between about 30% and 400% by weight of the therapeutic substance.
- 12. (previously presented) A formulation according to claim 1, wherein the propellant is alkane based.
- 13. (original) A formulation according to claim 12, wherein the propellant is at least one haloalkane.
- 14. (original) A formulation according to claim 13, wherein the propellant is selected from HFA-134a and HFA-227.

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15. (previously presented) A formulation according to claim 1, wherein at least one polyhydroxylated polyalkene has the general structure -(CH₂-CHOR)_n- where R is the same or different from one monomeric unit to the next, and is hydrogen, lower alkyl, lower alkenyl, lower alkanoyl, lower alenoyl or is a bridging group between adjacent monomers.

- 16. (original) A formulation according to claim 15, wherein, when R is not hydrogen, the number of carbon atoms, excluding any –CO- group, is between 1 and 6, inclusive.
- 17. (previously presented) A formulation according to claim 15, wherein the polyhydroxylated polyalkene is selected from polyvinylalcohol, polyvinylacetate, polyvinyl alcohol-co-vinyl acetate, poly(vinyl butyral), poly(vinyl alcohol-co-ethylene), and mixtures thereof.
- 18. (original) A formulation according to claim 17, wherein the polyhydroxylated polyalkene is PVA.
- 19. (previously presented) A formulation according to claim 18, wherein the PVA a hydrolysate of PVAc, the level of hydrolysis being between 40% and 100%.
- 20. (previously presented) A formulation according to claim 18, wherein the PVA a hydrolysate of PVAc, the level of hydrolysis being between 50 and 90%.
- 21. (previously presented) A formulation according to claim 18, wherein the PVA has a molecular weight of between about 9 kDa and 50 kDa.
- 22. (previously presented) A formulation according to claim 1, wherein the polyhydroxylated polyalkenes are present in an amount of from about 5% to about 200% by weight of the therapeutic substance.

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23. (original) A formulation according to claim 22, wherein the polyhydroxylated polyalkene is present between about 10% and about 50% by weight of the substance.

- 24. (currently amended) A method for the preparation of a formulation as defined in claim 1, comprising blending the therapeutic agent with the glycoside carbohydrate compound or derivative thereof and polyhydroxylated polyalkene substances in an aqueous vehicle, drying the resulting blend to a powder, and then formulating with propellant.
- 25. (original) A method according to claim 24, wherein the aqueous vehicle is selected from saline, a suitable buffer, and deionised water.
- 26. (previously presented) A method according to claim 24, which comprises spray—drying the blend.
- 27. (currently amended) A powdered formulation of a therapeutic agent, a glycoside carbohydrate compound or derivative thereof and a polyhydroxylated polyalkene, as defined in claims 1, which is suitable for incorporation with a haloalkane propellant for dispensing from a metered dose inhaler.
- 28. (original) A powdered formulation according to claim 27, wherein the powder particles have an aerodynamic diameter of between about $1\mu m$ and $50\mu m$.
- 29. (previously presented) A metered dose inhalation device provided with a reservoir comprising a formulation according to claim 1.